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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,401	07/18/2003	Craig A. Rosen	PZ020P2C1	6102

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,401	ROSEN ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-33 and 48-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-33 and 48-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 24-33 and 48-57 are pending.

Applicant's arguments, filed 9/20/05 have been fully considered, but are not persuasive.

Claim Rejections - 35 USC § 101/112

Claims 24-33 and 48-57 remain rejected under 35 U.S.C. ə 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or a well established utility for the reasons set forth in the previous office action.

The rejected claims are drawn to polypeptides, or specific portions of SEQ ID NO: 145, or the protein from the related deposit HFVAB79. Fusion proteins, compositions comprising carriers, and product-by process claims are included.

All of Applicant's arguments, attachments and cited prior art from all responses have been fully considered. Previous office actions have clearly set forth the facts of the disclosure regarding SEQ ID NO: 145 in the specification. Applicant argues that any polypeptide which may be expressed in a particular tissue or type of cell has utility. Exhibits A-D disclose various polypeptides. The fact that these polypeptides may have their own specific substantial and credible utility is not at issue here. The polypeptides of the claims are not those disclosed in Exhibits A-D.

35 USC 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every *use" that can be asserted will be sufficient to satisfy 35 USC 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy 35 USC 101 . See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, 35 USC 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 53445, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891): by evidence showing successful in

vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748), and by evidence showing in vivo antitumor activity In mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442). By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy 35 USC 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best ... on the way to discovering a practical utility for polypropylene at the time of the filing but not yet there. Ziegler, at 1203, 26 USPQ2d at 1605.

An invention certainly can have a utility that is shared by other compounds or compositions. Take, for example, an application that claims ibuprofen and discloses that it is useful as an analgesic. No one would argue that a claim to ibuprofen lacks utility simply because aspirin and acetaminophen are also useful as analgesics. On the other hand, not every utility will satisfy 101, even if the utility is shared by a class of inventions. Assume that the above-described application did not disclose that ibuprofen was an analgesic but only disclosed that it is useful because it can be used to fill a jar, which would then be useful as a paperweight. There would be little doubt that this disclosed utility would not satisfy 101, even though the utility is shared by a large class of Inventions, viz., those whose physical embodiments have mass. So while a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy 101.

Applicant argues is that the claimed polypeptides are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. Such a disclosure does not provide a "specific benefit in currently available form. Rather, the present case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id at 534, 148 USPQ at 695.

Applicant argues that the "only similar polypeptides are necessary" for the establishment of a well-established utility are ones useful as tissue specific markers for cancer. Applicant acknowledges that the cited proteins are not related in any way to the claimed polypeptides, other than that they are also polypeptides. Applicant has failed to demonstrate any sequence similarity or structural similarity between SEQ ID NO: 145 and any proteins known for the diagnosis, detection, prevention and/or treatment which are described in the specification or were well known at the art at the time of priority. The fact that they are all proteins is not sufficient. All of the references cited by Applicant in the response are to differing proteins having differing sequences, differing structures, and differing bodies of knowledge in the scientific community. Each protein cited appears to have been the subject of much study and analysis which is not set forth in the specification for the disclosed and claimed SEQ ID NO: 145. Applicant's arguments cannot take the place of evidence. In re Schulze,346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)

Applicant asserts that the disclosure of an expression pattern is the same as an activity. It is noted that no evidence exists in the record substantiating the asserted tissue specificity. It would appear the nucleotide encoding SEQ ID NO: 145 was assessed for tissue specificity, but not the polypeptide encoded by it. Not all polynucleotides that are produced by the cell are translated into polypeptides. Further, an activity is something the protein does in the cell in which is it expressed. Catalyzing an enzymatic reaction is one example. The specification, as filed, fails to identify any activity for the claimed polypeptides.

Applicant questions which aspect of the asserted utilities fail to meet the standard. As has been set forth previously, the polypeptide of SEQ ID NO: 145 does not have a specific, substantial and credible utility, and does not have a well-established utility according to 35 USC 101.

Applicant argues that the asserted expression pattern of the polynucleotide encoding the claimed polypeptide in a given tissue alone supports the asserted utility of diagnosis, detection, prevention and/or treatment of liver disorders. This is not persuasive, as the specification fails to provide any evidence that SEQ ID NO: 145 is related to any disorder or the liver.

Applicant argues the post-filing art supports the asserted utilities for the claimed sequence, however, as set forth previously, these publications set forth experiments, data and

procedures that go beyond those described in the specification. The specification does not set forth the experiments of Smith, or Roult that led to their conclusions.

Applicant is reminded that the utility requirement must be met as of the filing date of the application. See in re Brana, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed Cir. 1995) ("Enablement or utility is determined as of the application filing date."). An applicant cannot rely on post-filing advances in the art to supplement a disclosure that was inadequate at the time it was filed. See in re Glass, 492 F.2d 1228 1232 181 USOQ 31 34 CCPA 1974.)" "Application sufficiency under 112, first paragraph must be judged as of its filing date. It is an applicant's obligation to supply an enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file."

Applicant argues that the polypeptides can be used to generate antibodies that may have a further use. This is not persuasive. Further research utility is not deemed to meet the standard of specific, substantial and credible. There is no disclosed or real world utility associated with the claimed protein. Further experimentation is necessary to attribute a utility to the claimed protein. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). There are no actual antibodies to the claimed protein described in the specification. No evidence is of record which supports the assertion that the antibodies have a specific substantial and credible utility under 35 USC 101.

As set forth previously, the claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a real world use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification identifies SEQ ID NO: 145, the elected polypeptide sequence, as being related to "gene 7" at pages 28-30. SEQ ID NO: 145 is also referenced in the table at page 276.

At pages 28-30, the specification asserts that the polypeptide sequence encoded by "gene 7" is expressed primarily in the liver and testes.

At pages 28-30 the specification lists a variety of potential activities and tissue "specificities" that may be related to the elected sequence. Activities and specificities for the DNA and/or encoded protein listed in this section include: hepatic, endocrine and reproductive disorders, as well as immune system and hematopoetic system disorders. At no point is the specifically elected sequence tested for any of the listed associations, activities or expression patterns. At no point is a diagnostic test for any disease developed such that the elected sequence is shown to be linked diagnostically to a particular disease. Each of the above activities is very different, and they are substantially non-overlapping. One of skill in the art would not readily be able to determine a use for the claimed sequence upon reading the specification.

At pages 29-30, the specification sets forth a laundry list of potential uses for any potentially encoded protein involved in cell growth and differentiation, including "detection, treatment, and./or prevention of hepatoblastoma, jaundice, hepatitis or liver metabolic diseases and conditions that are attributable to the differentiation of hepatocyte progenitor cells" without specifically linking the claimed protein to any particular type of disorder, activation pathway or other activity. The list of potential uses include the disparate categories of testicular function, other reproductive disorders, inflammatory disorders, cancer, as well as the categories of "hypoproliferative disorders" and "Infectious diseases". Each of these categories of disease have widely varying etiology, causes, and treatments, and the specification provides no particular evidence linking the claimed protein to any particular disease, or even class of diseases.

The laundry list of potential activities pointed to by Applicant all are general in nature, many are conflicting, many have widely varying causes or effects such that upon reading the specification, one of skill in the art would not be readily able to determine a specific substantial and credible utility for the claimed polypeptides.

The specification was further probed for information as to a specific substantial and credible utility for the claimed peptide. At page 276, in the table, SEQ ID NO: 145 is identified as being encoded by SEQ ID NO: 17. The table asserts that the polypeptide has a signal sequence beginning with amino acid 1, and ending with amino acid 15, and asserts that the secreted portion would be from amino acids 16-194. This information was all generated by

computer analysis and has not been validated by producing the polypeptide in vitro and observing cleavage and secretion of the actual sequence. No such experiments are set forth in the specification as filed. No particular activities or functions are specifically linked to any form of the polypeptides being claimed.

Claims 24-33 and 48-57 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MARY K. ZEMAN
PRIMARY EXAMINER
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12/6/05